

REMARKS

The present Office Action addresses and rejects claims 1-30.

At the outset, Applicant would like to thank Examiner Brown for extending the courtesy of a telephone interview with Applicant's attorney on September 25, 2006. During the interview, the pending rejections and prior art were discussed. However, the Examiner and Applicant's attorney were unable to come to an agreement with respect to the appropriate interpretation of the prior art teachings and the patentability of the proposed amendments.

Claim Rejections – 35 U.S.C. § 103

Claims 1-30 are rejected pursuant to 35 U.S.C. § 103(a) as being unpatentable over Dreyfuss (U.S. Pub. No. 2003/0065361) in view of Gogolewski *et al.* (U.S. Pat. No. 5,236,431), along with Sasso *et al.*, (U.S. 2004/0225292).

Independent Claim 25

Despite Applicant's explanations that none of the cited references discloses or suggests positioning and fixing a tissue graft into a bone tunnel, the Examiner nonetheless rejects claim 25 on the grounds that it "doesn't positively recite the method step of inserting a tissue graft in position in a portion of a bone tunnel." (Final Office Action dated July 25, 2006, pg. 4). In support of this contention, as conveyed during the recent telephone interview, the Examiner argues that claim 25 states a method *for* attaching a tissue graft and not a method *of* attaching a tissue graft. On this basis, the Examiner maintains that the method step is not positively recited in the claims and thus, the prior art only has to be capable of performing this method.

Applicant respectfully disagrees.

Claim 25 recites:

"A method *for* attaching a tissue graft to bone, comprising:
forming a bone tunnel into bone;
providing a tissue fixation device in the form of an elongate member having a longitudinally oriented channel formed therein that extends from an opening in a proximal end thereof, the tissue fixation device having at least one opening formed in a

sidewall thereof that is in fluid communication with the channel;
positioning a portion of the tissue graft within the bone tunnel;
inserting the tissue fixation device within the bone tunnel to secure the tissue graft therein; and
injecting a treatment material into the channel of the tissue fixation device to enable the material to be secreted through the at least one opening to a region external to the sidewall of the tissue fixation device. (Emphasis added).

To being with, it is irrelevant whether claim 25 states “a method *for* attaching a tissue graft” or “a method *of* attaching a tissue graft.” The phrase “a method for attaching a tissue graft” as it appears in claim 25 is preamble language and in the instant case is neither limiting nor significant because, here, the preamble merely states the purpose or intended use of the invention rather than a distinct definition of any of the steps of the claimed invention. Thus, even if the preamble phrase is deleted, the method steps of claim 25 are not affected. (See MPEP § 2111.02; *Pittney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999); *Catalina Mktg. Int’l v. Coolsavings.com, Inc.*, 289 F.3d 801, 808-09 (Fed. Cir. 2002)).

Furthermore, the phrase “a method *for* attaching a tissue graft” and “a method *of* attaching a tissue graft” have the same implications. In both contexts the term “for” and “of” are used as a function word to indicate how to attach a tissue graft. (See e.g. MPEP § 2111.02 citing *Metabolite Labs., Inc. v. Corp. of Am. Holdings*, 370 F.3d 1354, 1358-62 (Fed. Cir. 2004) (the recitation of the intended use *of* “detecting” a vitamin deficiency in the preamble rendered the claimed invention a method *for* “detecting”) (Emphasis added)).

Therefore, irrespective of whether the preamble of claim 25 uses the term “for,” a plain reading of the body of claim 25 demonstrates that the method steps of “positioning a portion of the tissue graft within the bone tunnel” and “inserting the tissue fixation device within the bone tunnel to secure the tissue graft therein” are explicitly recited in claim 25. Thus, the claimed method specifically requires the steps of positioning a tissue graft in a bone tunnel and securing the tissue graft therein with a tissue fixation device.

Accordingly, because the cited references are devoid of any teaching or even suggestion of a method including the steps of fixing a tissue graft by placing the graft into a bone tunnel and securing the graft by inserting a tissue fixation device into the bone tunnel, claim 25, and the claims

that depend therefrom, distinguish over the cited prior art. Thus, Applicant respectfully requests withdrawal of the rejection of these claims in view of Dreyfuss, Gogolewski and Sasso.

Independent Claim 1

Claim 1 is directed to a bioimplantable tissue fixation device comprising an elongate body formed of a biocompatible, *bioresorbable* material. The body has an outer surface, a proximal end, a distal end and a longitudinal axis extending therethrough. An internal cavity extends into the body from an opening in the proximal end of the body and terminates proximal to the distal end. At least one opening is formed in the outer surface of the body, each of the at least one openings being in fluid communication with the internal cavity such that the internal cavity is able to accept a treatment material for delivery external to the outer surface of the body through the at least one opening.

The Examiner concurs that Dreyfuss fails to teach the use of a bioresorbable material, but continues to reject independent claim 1 on the grounds of obviousness. In support of his position, the Examiner states “if one of ordinary skill in the art wanted to allow the suture anchor to remain *permanently* in the body, yet eliminate the risk of causing harm to tissue, the suture anchor could be made of a bioresorbable material.” (Final Office Action dated July 25, 2006, pg. 4; emphasis added). The Examiner also points to Gogolewski as teaching a tissue fixation device made of a bioresorbable material; as well as arguing that it is “well known in the surgical fastener art to form a fastener of a bioresorbable material to prevent a surgeon from having to operate on a patient and remove the fastener after the healing process is completed.” (*Id.*)

Applicant respectfully disagrees.

At the outset, the Examiner’s statement is contradictory because if something were intended to remain in the body permanently it clearly *would not* be made of a bioresorbable material. Moreover, the Examiner cannot show obviousness of an invention simply by “decomposing an invention into its constituent elements, finding each element in the prior art, and then claiming that it is easy to reassemble these elements into the invention.” (*In re Mahurkar Patent Litigation*, 28 USPQ2d 1801 (N.D. Ill. 1993), *aff’d*, 37 USPQ2d 1138 (Fed. Cir. 1995)). That “is a forbidden *ex*

post analysis.” (*Id.*). As is made clear by Federal Circuit law, there must be some suggestion, teaching or motivation to combine prior art references. (*See e.g. In re Dembiczak*, 50 USPQ2d 1614 (Fed. Cir. 1999). Here, as previously contended by Applicant, no such teaching or motivation or even suggestion exists to combine Dreyfuss and Gogolewski.

To begin with, the Examiner’s reasoning ignores the fact that Dreyfuss’ inventive concept is directed *against* the use of bioabsorbable or biodegradable materials for its suture anchors. In particular, Dreyfuss is concerned with providing an apparatus for anchoring suture to bone that overcomes a variety of prior art problems, such as detachment of a suture from an anchor once the anchor is installed in bone. (*See* pg 1, paragraphs 13). To achieve this objective, Dreyfuss teaches a suture anchor being made of a biocompatible *metal*. (*See* pg 1, paragraph 15). Based on a plain reading of the teachings of Dreyfuss, one skilled in the art would understand that this reference teaches away from modifying the suture anchor by forming it of a biodegradable material. The Federal Circuit has made it clear that “references that teach away cannot serve to create a *prima facie* case of obviousness.” (*McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1354, 60 USPQ2d 1001 (Fed. Cir. 2001)).

Moreover, even if one formed the suture anchor of Dreyfuss from the resorbable material of Gogolewski, the resulting suture anchor would likely fail as a fixation device. Specifically, if the suture anchor of Dreyfuss were made with a bioabsorbable material, then when the anchor dissolves, the connection of the suture to the bone via the anchor can no longer be expected to exist. Thus, the means for securing the suture to the bone would be absent, and any tissue that was reattached to the bone via the suture would become detached. As such, any attempt to reconfigure Dreyfuss’ device to meet the claimed bioresorbable fixation device would be at odds with the disclosure of Dreyfuss.

Therefore, one skilled in the art would have no motivation to combine the references of Dreyfuss and Gogolewski, and would be unable to arrive at the claimed invention based on the teachings of these references. Thus, the only support for combining Dreyfuss and Gogolewski is by application of hindsight, which is clearly improper. (*See e.g., Ruiz v. A.B. Chance Co.*, 69 USPQ2d 1686 (Fed. Cir. 2004) (“hindsight reasoning, using the invention as a roadmap to find its prior art

components, would discount the value of combining various existing features or principles in a new way to achieve a new result--often the very definition of invention.'')).

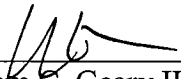
Accordingly, because none of the cited references, either alone or in combination teach the limitations of the claimed invention, Applicants respectfully request withdrawal of the rejection of claim 1. In addition, Applicants believe claims 2-24 are allowable at least because they depend from an allowable base claim.

CONCLUSION

In summary, it is believed that the amended claims are in condition for allowance, and reconsideration is respectfully requested for all the reasons set forth above. The Examiner is urged to telephone the undersigned Attorney for Applicants in the event that such communication is deemed to expedite prosecution of this matter.

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Respectfully submitted,

By 
William C. Geary III
Registration No.: 31,359
NUTTER MCCLENNEN & FISH LLP
World Trade Center West
155 Seaport Boulevard
Boston, Massachusetts 02210-2604
(617) 439-2766
(617) 319-9766
Attorney for Applicant